





## DEPARTMENT OF HEALTH &amp; HUMAN SERVICES

Public Health Service

Food and Drug Administration  
Rockville MD 20857

February 4, 2004

RE NDA 21-435ADMINISTRATIVE STAY OF ACTION

In light of questions raised about the source of the data the Food and Drug Administration (FDA) relied on in approving Dr. Reddy Laboratories Ltd's New Drug Application for Amvaz, amlodipine maleate (NDA 21-435), FDA believes that it is in the public interest to stay the effective date of the approval of that NDA pending FDA's reevaluation of the basis for that approval. Accordingly, the effective date of the approval of NDA 21-435, is hereby stayed until FDA has reevaluated the application and determined that the drug has been shown to be safe and effective under the conditions of use described in the labeling based on data from appropriate sources. Marketing under NDA 21-435 is prohibited during the pendency of the stay.

William K. Hubbard  
Associate Commissioner for Policy and Planning

EXHIBIT 1